

REMARKS

The Examiner is thanked for the due consideration given the application.

Claims 3, 5-10, 12, 17 and 18 are pending in the application. Claim 3 has been amended to not recite the treatment of atherosclerosis.

No new matter is believed to be added to the application by this amendment.

Rejection Under 35 USC §102(e)

Claims 3, 5-10, 12, 17 and 18 have been rejected under 35 USC §102(e) as being anticipated by McLachlan (U.S. Publication 20020166129). This rejection is respectfully traversed.

The present invention, as instantly claimed, pertains to a method of treating hypercholesterolemia or hyperlipidemia. This method entails orally administering a composition of β -casein where the β -casein is at least 95 wt% β -casein A². A serum level of any one or more of:

- a) cholesterol;
- b) low density lipoprotein (LDL) cholesterol relative to high density lipoprotein (HDL) cholesterol;
- c) low density lipoprotein (LDL) cholesterol;
- d) very low density lipoprotein (VLDL) cholesterol;
- e) apolipoprotein B; or

f) triglycerides.

After administration the serum level of the composition is lower than the serum level before administration of the composition. See instant claim 3.

McLachlan pertains to milk and milk products for preventing or treating heart disease. McLachlan utilizes milk which is free of β -casein A¹ protein in the prevention or treatment of coronary heart disease. In addition, a process for the testing of DNA from cells obtained from lactating bovines for the presence of DNA encoding certain β -casein proteins, selecting the bovines on the basis of the testing, and then milking those bovines to produce milk free of β -casein A¹ for use in the prevention or treatment of coronary heart disease is disclosed. See Abstract.

McLachlan does not teach or suggest in any way the treatment of hypercholesterolemia or hyperlipidemia. McLachlan teaches the treatment of coronary heart disease, but this is not the same thing as the treatment of hypercholesterolemia or hyperlipidemia.

The Office Action points to page 3, paragraph 0066 for a teaching that arteriosclerosis is treated. Paragraph 0066 of McLachlan merely states: *"Coronary heart disease means any disease or disorder relating to the coronary heart system and includes atherosclerosis and ischaemic heart disease."*

However, hypercholesterolemia or hyperlipidemia cannot be equated to heart disease, despite the possibility of being contributing factors to heart disease.

For example, atherosclerosis is a disease of large and medium-sized muscular arteries. Atherosclerosis is characterized by plaque formation, vascular remodeling, acute and chronic luminal obstruction, abnormalities of blood flow, and diminished oxygen supply to target organs.

In contrast, hyperlipidemia means that the patient has high cholesterol and high triglyceride levels. Similarly, hypercholesterolemia means high cholesterol in the blood.

Although hypercholesterolemia or hyperlipidemia may be a contributing factor to atherosclerosis, it does not follow that a treatment for hypercholesterolemia or hyperlipidemia will be an effective treatment for atherosclerosis and vice versa. For example, stents for vascular surgery may be used to treat atherosclerosis, but these treatments would have no effect on hypercholesterolemia or hyperlipidemia. On the other hand, reducing cholesterol or lipid levels may not affect an already damaged vascular structure.

As a result, McLachlan does not anticipate independent claim 3 of the present invention, which is specifically directed to hypercholesterolemia or hyperlipidemia. Claims depending upon claim 3 are patentable over McLachlan for at least the above reasons.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Conclusion

If this amendment does not instantly place the application in condition for allowance, the Examiner is respectfully requested to contact Robert E. Goozner, Ph.D. at the telephone number below to discuss the application.

Prior art cited but not utilized is believed to be non-pertinent to the instant claims.

The objections and rejection are believed to have been overcome, obviated or rendered moot and that no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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